DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 18, 2014

Comecer Netherlands b.v.
% Mr. Thomas Kroenke
Principal Correspondent
Speed To Market, Inc.
P.O. Box 3018
NEDERLAND CO 80466

Re: K142325
Trade/Device Name: Veenstra Instruments
Regulation Number: 21 CFR 892.1360
Regulation Name: Radionuclide dose calibrator
Regulatory Class: II
Product Code: KPT
Dated: August 22, 2014
Received: August 25, 2014

Dear Mr. Kroenke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142325

Device Name
Veenstra Instruments VDC-506 Dose Calibrator

Indications for Use *(Describe)*
The Veenstra Instruments VDC-506 Dose Calibrator is designed to measure the amount of radioactive material in vials, syringes and capsules. It is used to measure the amount of activity used to prepare radiopharmaceutical kits, measure the activity in syringes of radiopharmaceuticals prior to injection and to quantify the activity remaining in the syringe following injection. It is indicated for use in the preparation of radiopharmaceuticals and verification of the activity prior to patient administration.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submission Date:	14 August 2014
Submitter:	Comecer Netherlands b.v. Madam Curieweg 1 Joure, Fryslan 8501 XC The Netherlands
Submitter Contact:	Mr. Gert Jan Klok Phone: +011 031-513-416964 Fax: +011 031-513-416919 Email: gklok@comecer.com
Application Correspondent:	Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA Mr. Thomas Kroenke Phone: +1 (303) 956-4232 Fax: +1 (303) 642-3141 Email: tkroenke@speedtomarket.net
Manufacturing Site:	Comecer Netherlands b.v. Madam Curieweg 1 Joure, Fryslan 8501 XC The Netherlands
Trade Name:	Veenstra Instruments VDC-506 Dose Calibrator
Common Name:	Radionuclide dose calibrator
Classification Name:	Radionuclide dose calibrator
Classification Regulation:	21 CFR §892.1360
Product Code:	KPT

Substantially Equivalent Devices:	*New Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Veenstra Instruments VDC-506 Dose Calibrator	K030066	Nuclear Associates Cal/Rad Mark VI/VDC-505 Dose Calibrator, Model 34-165

510(k) Summary

Device Description: The Veenstra Instruments VDC-506 Dose Calibrator (VDC-506) is a software application installed on a personal computer (PC) running Windows XP, and is used in conjunction with the Veenstra Instruments VIK-202 ionization chamber (VIK-202) to measure the radioactive strength of radioactive material in vials, syringes and ampoules placed inside the ionization chamber.

The VDC-506 software, in conjunction with the PC, serves as the control mechanism and display for the VIK-202 ionization chamber. The PC on which the VDC-506 software is installed is connected to the VIK-202 ionization chamber using a RS-232 cable.

It is recommended that the PC includes a touchscreen display for convenient navigation within the software; however, a touchscreen is not necessary.

Intended Use: The Veenstra Instruments VDC-506 Dose Calibrator is designed to measure the amount of radioactive material in vials, syringes and capsules. It is used to measure the amount of activity used to prepare radiopharmaceutical kits, measure the activity in syringes of radiopharmaceuticals prior to injection and to quantify the activity remaining in the syringe following injection. It is indicated for use in the preparation of radiopharmaceuticals and verification of the activity prior to patient administration.

510(k) Summary

Technology Comparison:

The VDC-506 employs the same technological characteristics as the predicate device.

Characteristic	*Predicate Device*	*Proposed Device*
Controller/ Display Unit	Control Unit which contains a single board computer.	Personal computer (PC)
Controller/ Display Unit Operating System	Microsoft® Windows XP Embedded	Microsoft® Windows XP for PC or higher
VDC-506 Readout	0.001 MBq – 200 GBq 0.01 μCi – 6000 mCi	Same
VDC-506 Software Features	Future Dose Calculator QA Protocols for Daily and Quarterly Checks Mo-99 Breakthrough Protocol	Same
Ionization Chamber Model	Veenstra Instruments VIK-202	Same
Chamber Type	Argon-filled, pressurized, well chamber	Same
Ionization Voltage	150 V lithium battery	Same
Overall Accuracy	± 3 % dependant of specific calibration source and geometric variations	Same
Electrometer Accuracy	± 1 %	Same
Temperature Coefficient	0.1 % / ° C between 10° C and 40° C at 5 MBq and up	Same
Reproducibility	± 1% over 24 hours, stable conditions	Same
Reproducibility	± 1% over 24 hours, stable conditions	Same
Geometry of the Sensitive Volume (Well Size)	Height: 250 mm (~9.84 in) Diameter: 60 mm (~2.36 in)	Same
Linearity	± 1 % between 1 MBq and 200 GBq (Tc-99m)	Same

510(k) Summary

Summary of Performance Testing:

Electrical Safety

The VIK-202 ionization chamber was tested for performance in accordance with the following Standards:

- *IEC 60601-1: 2005, Medical electrical equipment – Part 1. General requirements for basic safety and essential performance*

Test results indicated that the VIK-202 complies with the Standards.

Electromagnetic Compatibility (EMC) Testing

The VIK-202 ionization chamber was tested for performance in accordance with the following Standard:

- *IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*

Test results indicated that the VIK-202 complies with the Standards.

Software Testing

Software device modifications made to the VDC-506 system were designed and developed according to a robust software development process, and were rigorously verified and validated.

Software information is provided in accordance with internal documentation and the following Standards and guidance documents:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99; and*
- *IEC 62304: 2006, Medical device software – Software life cycle processes.*

Test results indicate that the VDC-506 complies with its predetermined specification and the Standards and guidance documents.

510(k) Summary

Performance Testing

The VDC-506 system and VIK-202 ionization chamber were verified for performance in accordance with internal documentation and the following Standards:

- *IEC 61145: 1992, Calibration and usage of ionization chamber systems for assay of radionuclides;*
- *IEC 61303: 1994, Medical electrical equipment – Radionuclide calibrators – Particular methods for describing performance; and*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices.*

Test results indicated that the VDC-506 system and VIK-202 comply with predetermined specification and with the applicable Standards.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the software device modifications made to the VDC-506 system. The results of these activities demonstrate that the VDC-506 system is safe and effective when used in accordance with its intended use and labeling.

Therefore, the VDC-506 system is considered substantially equivalent to the predicate device.